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54 FR 37208-01

54 FR 37208-01, 1989 WL 288197 (F.R.)

**(Cite as: 54 FR 37208)**

PROPOSED RULES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 414

[BPD-614-P]

RIN 0938-AD99

# Medicare Program; Payment for Covered Outpatient Drugs

Thursday, September 7, 1989

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth the methodology for determining payment for covered outpatient drugs under the new catastrophic drug benefit. This proposal would implement sections 1834(c) (2), (3), and (4) of the Social Security Act as added by section 202(b) of the Medicare Catastrophic Coverage Act of 1988. Coverage of and payment for these covered outpatient drugs under Part B of Medicare would be implemented on January 1, 1990 for drugs used in immunosuppressive therapy and covered home intravenous (IV) drugs and on January 1, 1991 for all other drugs.

DATE: To be considered, comments must be mailed or delivered to the appropriate address, as provided below, and must be received by 5:00 p.m. on November 6, 1989.

ADDRESS: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-614-P, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Ave. SW., Washington, DC.

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

Due to staffing and resource limitations, we cannot accept facsimile (FAX) copies of comments.

the average prices for a drug product. As we stated above, we intend to make the determination of the average price component on a national basis.

a. Biannual Survey. Under section 1834(c)(3)(C)(ii)(I) of the Act, the Secretary must conduct a biannual survey of nonmultiple-source drugs to determine the per dosage unit average price for the drug. However, the Secretary need not conduct a survey if--

- During 1990, the Secretary determines that a survey is not appropriate for a specific covered outpatient drug; or

- After 1990, there is a low volume of sales for the drug or there are other ***37214** appropriate reasons not to conduct a survey.

Under section 1834(c)(3)(C)(ii)(II) of the Act, for multiple-source drugs, the Secretary may base the per dosage unit average price for the drug on either the published average price for the drug or on a biannual survey.

The biannual surveys must be based on prices in effect the first day of the previous payment calculation period. For example, for drugs dispensed on or after January 1, 1991 and before July 1, 1991, the survey must be based on prices in effect on July 1, 1990. In addition, the biannual surveys must be based on a representative sample of direct sellers, wholesalers, or pharmacies (as appropriate) of wholesale or comparable direct prices excluding discounts to pharmacies. That is, in determining the average price, the Secretary cannot take into account any discount provided to a pharmacy.

We are considering use of a survey for multiple-source drugs that are commonly prescribed to Medicare beneficiaries. We intend to conduct the survey on a selected basis because we believe that the survey results may give a more accurate reflection of prices (exclusive of discounts) of prescription drugs compared to the published average prices in the comprehensive listings. The extent of the survey would be determined on an on-going basis. As required by section 1834(c)(3)(B)(ii) of the Act, we would use the unweighted median of the surveyed prices. We also intend to limit the survey of nonmultiple-source drugs to those drugs that are more commonly prescribed to Medicare beneficiaries. In this case, we would use the median of the surveyed prices.

Any survey that we conduct would use statistically valid methods of sampling, estimation, and imputation in order to establish the drug prices in effect for the payment calculation period.

Section 1834(c)(3)(C)(ii) of the Act specifies that discounts to pharmacies should not be considered in determining the average price. There is a common billing practice of showing both suggested list price and the wholesaler's or manufacturer's actual selling price on invoices. For example, an invoice has one column marked "suggested list price," "list AWP," or a similar phrase. A second column is marked "actual cost" or "price." We would use the actual selling prices

(before discounts) for purposes of the survey because the suggested list prices (or list AWP) are essentially comparative prices to demonstrate that when the purchaser pays the actual selling price, the purchaser pays less than the suggested list prices. The actual selling price is the price at which the drug product is generally available to pharmacies, either from a wholesaler or a manufacturer.

For determining survey prices, we would use the generally available selling price instead of the "list average wholesale price (AWP)" because we believe this is consistent with Congressional intent. The Conference Report states that the survey "is vital to ensuring the integrity of reimbursement limits" and, to that end, Congress gave the Secretary the authority to impose civil monetary penalties if a wholesaler or direct seller refuses to provide information to the Secretary or provide false information. (H.R. Rep. No. 661, 100th Cong., 2d Sess. 189 (1988).) Implicit in the statement that the survey is vital to the integrity of payment limits and in the provisions for civil monetary penalties is the assumption that the prices to be derived from the survey will be more accurate and, in all likelihood, lower than the prices in the nationally recognized comprehensive published price listings.

The "list AWP" on invoices sampled for the survey activity is the same as or similar to the average wholesale price in the published price listings. There would be no value in conducting a survey of this nature if it would be merely an exercise in gathering data already available in the published price listings. In addition, there would be no purpose in expending public funds to carry out the survey if it duplicates price information that is already publicly available. There would also seem to be no purpose in Congress giving the Secretary authority to impose civil monetary penalties for refusal to provide information or provision of false information if we would only be gathering price information that is already available. We are, however, specifically requesting comments on using the generally available selling price in determining survey prices.

b. Published Average Price. We intend to use the Red Book published by Medical Economics, the American Druggist Blue Book (Blue Book) published by the Hearst Corporation, and prices published by Medi-Span, Inc. (Medi-Span) for determinations of published average price. In developing the unweighted median of the published average prices for a multiple-source drug without a restrictive prescription, we would array the average prices from these three publications. If there is a difference in the published listings of a distributor's price, we would use the lowest price.

For nonmultiple-source drugs and multiple-source drugs with a restrictive prescription, we would use the lowest published price from the sources listed above, as stated in the Conference Report (H.R. Rep. No. 661, 100th Cong. 2nd Sess. 189 (1988)).

c. New Therapeutically Equivalent Drugs. If drugs are added to the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations,"

during a 6-month payment calculation period, the following would apply:

- If addition of a drug changes the status of the drug from a nonmultiple-source drug to a multiple-source drug, we would recompute the dosage unit average price. The new dosage unit average price would be reflected in payments within 1 month of when the FDA published the addition of a therapeutically equivalent product in "Approval Drug Products with Therapeutic Equivalence Evaluations."

- If a drug was already a multiple-source drug at the beginning of the payment calculation period, we do not anticipate making any adjustment to the dosage unit average price. Of course, after the 6-month payment calculation period in which a drug is added to "Approved Drug Products with Therapeutic Equivalence Evaluations," we would consider the pricing information for the drug just as we consider pricing information for other drugs.

We believe that these decisions on how to handle additions to "Approved Drug Products with Therapeutic Equivalence Evaluations" would be reasonable. In the case of a drug that becomes a multiple-source drug during the payment calculation period, the price at which a therapeutically equivalent product is available is likely to be less. We believe that these potential price reductions should be incorporated into Medicare payments. For a drug that was already a multiple-source drug, we believe the addition of another drug product is less likely to modify the Medicare payment limits in a significant way.

5. Determining the 90th Percentile of Actual Charges

Under section 1834(c)(3)(A)(i) of the Act, the Secretary computes the 90th percentile of actual charges on any geographic basis that he determines to be appropriate, for example, carrierwide or statewide. The most administratively feasible bases for these computations would be carrierwide or national. We considered using a carrierwide basis, that is, calculating the 90th percentile in ***37215** each of the drug bill processor regions. However, we are proposing to use a national basis for determining the 90th percentile of actual charges because the other payment limit component (the administrative allowance plus the product of the number of tablets or other dosage units dispensed and the per dosage unit average price for the drug) would also be computed on a national basis. We believe that using two nationally based amounts would yield the most equitable comparison. We are, however, interested in receiving comments on the advisability of using a carrierwide basis instead of a national basis for these computations.

The determination of the 90th percentile of actual charges would be made on a per dosage unit basis taking into consideration the dosage form and strength.

*D. Nontherapeutically Equivalent Drugs*

In classifying generic drugs, the FDA uses two categories. The A category includes drug products that are considered to be therapeutically equivalent to